IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: EIS-SCHWARTZ35

In re Application of:	)	Conf. No.: 5208
	)	
Michal EISENBACH-SCHWARTZ et al	)	Art Unit: 1633
	)	
Appln. No.: 10/509,180	)	Examiner: K. K. Hill
	)	
Filed: April 27, 2005	)	Washington, D.C.
	)	
For: USE OF AN ORGAN-SPECIFIC SELF-PATHOGEN FOR TREATMENT OF A …	)	November 10, 2008

RESPONSE

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Randolph Building, Mail Stop Amendments
401 Dulany Street
Alexandria, VA 22314

Sir:

The present communication is responsive to the official action of July 10, 2008. Claims 37 and 40-43 presently appear in this case. Claims 37, 40 and 41 have been withdrawn from consideration. No claims have been allowed. The official action of July 10, 2008, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for treating a disease, disorder or injury in the eye, which is other than an autoimmune disease of the eye. The disease, disorder or injury is treated by immunizing the individual

having such a disease, disorder or injury with a peptide within the sequence of the pathogenic self antigen S-Ag or a modification thereof. The claims specify the preferred peptides to be administered. Preferably, the disease, disorder or injury is glaucoma.

Claims 37, 40 and 41 remain withdrawn from consideration. However, if present claim 43 is found to be allowable, then it is expected that claims 37, 40 and 41 will be rejoined and also found to be allowable.

Claims 42 and 43 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Schori and Singh. The examiner states that Schori teaches a method for treating a disease, disorder or injury in the eye that is other than an autoimmune disease by immunizing with a non-pathogenic Cop-1 peptide that provides protection from RGC death induced by ocular hypertension in the rat model of glaucoma. The examiner also states that Cop-1 is protective for optic nerve crush injury and ocular hypertension. The examiner recognizes that Schori does not teach the non-pathogenic antigen to be from S-antigen. However, the examiner states that at the time of the invention, Singh taught that the peptide of the present SEQ ID NO:5 could block experimental uveitis, and thus may have potential for the treatment of the eye. The examiner states that it would have been obvious to try substituting the peptide

of Schori with the peptide of Singh for the treatment of an eye disease such as glaucoma, because the simple substitution of one known element for another would have yielded predicable results to one of ordinary skill in the art at the time of the invention. It is noted that the examiner has a quotation with respect to the rejection, but does not indicate where this quotation is taken from. The examiner states that an artisan would be motivated to try substituting the peptide of Schori with the peptide of Singh for the treatment of an eye disease such as glaucoma, because the art has long recognized that uveitis includes specific diseases such as glaucoma, and thus it would naturally flow that administration for the peptide of Singh capable of blocking uveitis would also treat a patient suffering from ocular nerve injury or ocular hypertension such as glaucoma. This rejection is respectfully traversed.

First, applicant traverses to the examiner's statement that "the art has long recognized that intraocular inflammation (uveitis) includes specific diseases such as glaucoma." Singh does not teach that the peptide of SEQ ID NO:5 is capable of blocking **any** type of intraocular inflammation. Singh is specifically directed to the treatment of autoimmune uveitis. Glaucoma is not a species of autoimmune uveitis. Glaucoma is not an autoimmune disease at all. Singh only teaches the treatment of autoimmune diseases. If the examiner does not

agree with this traversal, it is requested that the examiner specifically cite literature to the contrary that would support the examiner's statement.

The use of "altered" peptides derived from antigens that cause autoimmune disease for treatment of the same autoimmune disease was a well known and accepted idea at the time of the invention. For, example, U.S. 5,948,764 discloses methods for treatment of multiple sclerosis utilizing altered peptides of human myelin basic protein, one of the antigens that causes multiple sclerosis. Thus, it may have been obvious to use an altered S-Ag peptide for treatment of autoimmune uveitis, an autoimmune disease of the eye caused by the S-Ag antigen, as disclosed by Singh. In contrast, it has been found in accordance with the present invention that this same altered peptide derived from S-Ag, may be used to treat a disease of the eye that is not autoimmune uveitis, or any autoimmune disease at all.

Neither Singh nor the entire literature in this active field disclose or suggest that a modified peptide derived from an antigen that causes an autoimmune disease, such as S-Ag peptide, may be used to treat a disease of the same organ that is not an autoimmune disease. Accordingly, a person skilled in the art had no good reason to pursue such option as alleged by the examiner, because there was not such an option available in

the state of the art. Consequently, there was no motivation to a person of ordinary skill in the art to try to replace Cop-1 with an altered S-Ag peptide for this purpose.

The examiner states that it would be obvious to try substituting the peptide of Schori with the peptide of Singh for the treatment of glaucoma. The examiner does not specifically cite *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (US 2007), but it is apparent that the examiner is using language found in that case. However, *KSR* does not stand for the principle that everything that would be obvious to try would be obvious in the sense of 35 U.S.C. 103. Indeed, *KSR*'s analysis of obvious to try states, 82 USPQ2d at 1390:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp.

This statement of the Supreme Court has recently been analyzed by the Federal Circuit in *Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd.*, 87 USPQ2d 1452 (Fed Cir. 2008). Citing this portion of *KSR*, the court stated at 1456-1457:

> The Supreme Court's analysis in *KSR* thus relies on several assumptions about the prior art landscape. First, *KSR* assumes a starting reference point or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, KSR presupposes that the record up to the time of invention would give some reasons, available within the

> knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. … Third, the Supreme Court's analysis in *KSR* presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified, predictable solutions," 127 S. Ct. at 1742. *In Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008), this court further explained that this "easily traversed, small and finite number of alternatives . . . might support an inference of obviousness." To the extent an art is unpredictable, as the chemical arts often are, KSR's focus on these "identified, predictable solutions" may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.

Clearly, this is not a situation where there is pressure to solve a problem and there are a finite number of identified predictable solutions. The solution of the present invention is not one of a finite number of identified predictable solutions. Indeed, for the reasons discussed above, the solution is not predictable at all. Singh only teaches that an altered peptide of an autoimmune peptide active in a specific autoimmune disease might be useful in treating that autoimmune disease. There is no motivation whatsoever to use such an altered peptide of an antigen in the eye to treat a disease of the eye that is not an autoimmune disease. "Obvious to try" is not a proper theory of obviousness in such a situation.

The *KSR* case does not change the previous case law about obvious to try in situations other than those in which

there are a finite number of identified predictable solutions. Here, to establish a *prima facie* case of obviousness, the examiner must establish that there is a reasonable expectation of success, i.e., that the result achieved would have been predictable. The examiner certainly cannot allege any reasonable expectation of success for use of a peptide specifically designed to treat a specific autoimmune disease of the eye, to treat any other non-autoimmune disease of the eye. Accordingly, reconsideration and withdrawal of this rejection is respectfully urged.

It is submitted that all of the clams now present in the case clearly define over the references of record and fully comply with 35 U.S.C. 112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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